

Notice of Allowability

Application No.

09/576,989

Applicant(s)

RICE ET AL.

Examiner

Art Unit

Zachariah Lucas

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview March 30, 2005.
2. ☒ The allowed claim(s) is/are 1,3-6,9,29,61,62,69,70,72,73 and 86-106.
3. ☒ The drawings filed on 04 December 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>3/30/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. Currently, claims 1, 3-6, 9, 29, 61, 62, 69, 70, 72, 73, and 86-106 are pending and under consideration in the application.
2. Amended claims 69, 70, 100, and 101 are directed, in part, to inventions that are independent or distinct from the invention originally claimed for the following reasons: These claims are directed in part to transgenic organisms, or to cells engrafted into a host organism, each of which is considered to be a distinct invention from the isolated polynucleotide (or isolated host cells comprising such). Such inventions have are recognized as having a different status in the art, require searches that are not required for the other inventions, and involve different issues of patentability from the previously examined claims directed to isolated polynucleotides and isolated host cells thereof.
3. In view of the amendments to the claims in the Response of March 3, 2005, and in view of the cancellation of the non-elected subject matter as indicated below from the pending claims, pursuant to the Interview Summary of March 30, 2005, claims 1, 3-6, 9, 29, 61, 62, 69, 70, 72, 73, and 86-106 are allowed.

EXAMINER'S AMENDMENT

4. In view of the presence of the non-elected subject matter, and the withdrawal of the rejections of record (below), the Examiner contacted the Applicant for permission to cancel the non-elected subject matter for purposes of immediate allowance. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an

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amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given by David Jenkins on March 30, 2005.

The application has been amended as follows:

Claim 69 is amended to delete the phrase "or a non-human transgenic organism" in line 1 of the claim.

Claim 70 is amended to delete the phrase "or an isolated host cell engrafted in a host organism" in lines 1-2 of the claim.

Claim 100 is amended to delete the phrase "or a non-human transgenic organism" in line 1 of the claim.

Claim 101 is amended to delete the phrase "or an isolated host cell engrafted in a host organism" in lines 1-2 of the claim.

These amendments were made for the purpose of removing non-elected subject matter from the application for the purposes of allowance. Because the cancelled subject matter is drawn to non-elected subject matter, the Applicant preserves the right to pursue such inventions in later filed applications.

5. Claims 1, 3-6, 9, 29, 61, 62, 69, 70, 72, 73, and 86-106 are allowed.

Claim Objections

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6. **(Prior Rejection-Withdrawn)** Claim 13 was objected to because of the following informalities: the claim reads on a mutation within “20 nt” of the ISDR. In view of the cancellation of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 101

7. **(Prior Rejection-Withdrawn)** Claims 69, 70, 72, and 73 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In view of the amendment of the claims to read on isolated host cells, and the cancellation of the other subject matter as non-elected, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

8. **(Prior Rejection-Withdrawn)** Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been cancelled from the application; the rejection is therefore withdrawn.

9. **(Prior Rejection-Withdrawn)** Claims 1, 3-8, 9, 12, 13, 15-16, 29, 61, 62, 69, 70, 72, 73, and 87 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed polynucleotides wherein the adaptive mutation is made to an HCV sequence from a HCV subtype 1b, does not reasonably provide enablement for polynucleotides to any HCV sequence. In view of the limitation of the claims to mutations in HCV subtype 1b, the rejection is withdrawn.

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10. **(Prior Rejection-Withdrawn)** Claims 1, 3-8, 9, 12, 13, 15-16, 29, 61, 62, 69, 70, 72, 73, and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the amendment of the claims to read on HVC subtype 1b with specific mutations, the rejection is withdrawn.

11. **(Prior Rejection-Withdrawn)** Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed polynucleotides comprising an adaptive mutation in the NS5a, does not reasonably provide enablement for any such polynucleotide wherein the polynucleotide is “capable of replication in a non-hepatic cell,” or for embodiments wherein any HCV polynucleotide is capable of replication in a HeLa cell. In view of the limitation of the claims to HCV subtype 1b and the identification of specific mutations, the rejection is withdrawn.

12. **(Prior Rejection-Withdrawn)** Claims 69, 70, 72, and 73 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated host cells comprising the claimed vector, does not reasonably provide enablement for host cells comprised within either the human patient or the transgenic animal for the reasons set forth below. In view of the cancellation of the rejected subject matter as being drawn to non-elected inventions, the rejection is withdrawn.

Claim Rejections - 35 USC §§ 102 & 103

13. **(Prior Rejections-Withdrawn)** Claims 1, 61, 62, 70, 72, 73, and 87 were rejected under 35 U.S.C. 102(e) as being anticipated by, and claims 3-6, 12, 13, 15, 16, and 29 as obvious over, Bartenschlager et al., (U.S. 6,630,343). In view of the amendment of the claims, such that they now require the mutations recited in prior claims 14 and 17 (previously indicated to be free of the art), the rejections are withdrawn.

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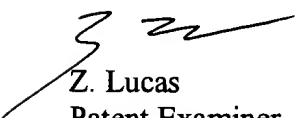
14. **(Prior Rejection- Withdrawn)** Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bartenschlager as applied above. In view of the amendment of the claim such that it now requires the mutations recited in prior claims 14 and 17 (previously indicated to be free of the art), the rejection is withdrawn.


Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


James C. Housel
4/4/05
